REMARKS

Applicants thank the Examiner for efforts in searching and examining this application to date. Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Two paragraphs in the specification are amended in accordance with the Examiner's recommendations.

Claims 2, 6, 18 and 19 are cancelled without prejudice or disclaimer. Claims 1, 3-5, 7-8, 10-14, and 16-17 are amended to recite specific embodiments. Claim 21 is added to recite embodiments previously recited in claim 16. These amendments are made without prejudice or disclaimer, and Applicants reserve the right to pursue any canceled subject matter in one or more continuing applications with the same rights of priority as the instant application. No new matter has been added by these amendments.

In claims 1, 4-5, 10-12, and 16-17, the claimed physiologically active agent is amended to be a "drug." Exemplary support for this limitation may be found in the specification, for example, on page 1, lines 5-10; and from page 6, line 27 to page 16, line 16. For the amendments to claims 1, 4, and 5, please also refer to the exemplary support provided in the originally filed application on, for example, page 6, lines 5-10; page 17, lines 24-29; Figure 1; page 21, line 20 to page 22, line 15; and claims 2, 6 and 8. For the amendment to claim 16, please also refer to the exemplary support provided in the originally filed application on, for example, page 18, line 14 to page 19, line 10; and Figure 2. Claims 2-5, 7, and 12-14 are also amended to conform to the amendments to claim 1 and correct informalities. Claim 8 is amended to conform to the amendments to claim 1.

After entry of these amendments, claims 1-5, 7-17 and 21 will be pending, with claims 1, 5, and 16 being the independent claims. These claims are presented for reconsideration.

OBJECTIONS TO THE SPECIFICATION AND CLAIMS

The Examiner objected to two informalities in the specification. Applicants have supplied replacement paragraphs that they believe conform to the Examiner's recommendations. Applicants therefore respectfully request withdrawal of the objections to the specification.

The Examiner also objected to informalities in claims 2-5, 7, 12-14, and 18. Claims 2-5, 7, and 12-14 have been amended to correct these informalities; claim 18 has been cancelled. Applicants therefore respectfully request withdrawal of the objections to claims 2-5, 7, 12-14, and 18.

With regard to the Markush language recited in claims 13 and 14, although Applicants have made the suggested amendments, Applicants respectfully refer to MPEP 803.02 and 2173.05(h), which indicate that "selected from ***the*** group consisting of" is proper Markush language.

CLAIM REJECTIONS UNDER 35 U.S.C. § 102

Claims 1-5, 11-12, and 16-17 are rejected under §102 as allegedly anticipated by U.S. 2002/0128579 by Church. Applicants respectfully traverse this rejection in as much as it may be applied to the pending claims.

As noted above, the pending claims are directed to methods for inhibiting the percutaneous absorption of a drug that has been topically administered (claim 1), removal of a drug from a reservoir thereof within the skin of a subject following transdermal administration of the drug (claim 5) and reducing the effect of overdose via transdermal administration of a drug to a site of skin of a subject to form a reservoir (claim 16). Church does not teach or suggest such methods.

Church relates to a patch for topical application to the skin, where the patch includes a charcoal based composition. The patch is used to remove ***toxins*** such as poisons, bacteria, fungus, carcinogens or other harmful pathogens from the skin which may be present due to insect bites or stings, or by contact with poisonous plants. The toxins removed by Church are distinguishable from the drugs recited in the instant claims, and there is no teaching or suggestion in Church that its charcoal patch would be useful for inhibiting the percutaneous absorption of or removing a drug that has been topically or transdermally administered, as recited in the instant claims.

Church also discloses that its charcoal patch may be used to reduce swelling of the skin by absorbing excess tissue fluid and products of inflammation. However, this disclosure also is unrelated to the subject matter of the pending claims.

Further, Church does not disclose a device comprising a membrane that comprises, on its skin contacting side, a layer of an adhesive that is permeable to the drug, or application of such a device such that drug is extracted from the skin through the layer of adhesive. Instead, Church describes an outer adhesive 7 surrounding a porous envelope 3 that contains activated charcoal (paragraph 28) and an adhesive on a peripheral zone 25 surrounding an activated charcoal composition 26 (paragraph 30 and claim 11). Church describes the activated charcoal as directly contacting the skin or being contained in a porous envelope or sheet that contacts the skin (paragraphs 28, 30, and 32). The porous envelope is made of paper, gauze, or felt (paragraphs 18, 28, and 32).

Regarding independent claim 1, Church further does not disclose a method of inhibiting percutaneous absorption of a drug that has been topically administered to a subject and wherein the subject has been administered an overdose of the drug or has experienced one or more adverse side effects from the drug.

Regarding independent claim 5, Church further does not disclose a method of removing a drug from a reservoir thereof in the skin.

Regarding independent claim 16, Church further does not disclose a method of reducing the effect of overdose of transdermally administered drug.

Because Church does not disclose several elements of each of the independent claims, it cannot anticipate the rejected claims. Applicants therefore respectfully request withdrawal of the §102 rejections based on Church.

CLAIM REJECTIONS UNDER 35 U.S.C. § 103

Applicants note generally that all of the claims rejected under § 103 depend from independent claims 1, 5, and 16. However, the secondary references cited in the §103 rejections do not cure the inability of Church to anticipate the methods recited in the independent claims. Thus, combining these references with Church fails to establish even a prima facie case of obviousness. Additional arguments pertinent to each of the individual § 103 rejections follow.

Claim 9 is rejected as being obvious in view of Church. Applicants respectfully traverse.

Claim 9 recites that the membrane is less than 2 mm thick. The Office Action asserts that it would have been obvious to "optimize" the thickness of Church's device to arrive at the embodiment of claim 9. However, as noted above, Church fails to teach other aspects of independent claim 1, from which claim 9 depends, thus the record does not establish a prima facie case of obviousness of claim 9. Applicants therefore respectfully request withdrawal of the § 103 rejection of claim 9.

Claims 6-8, 13, 14, 18, and 19 are rejected as being obvious over Church in view of U.S. 2002/0115957 by Sun et al. Applicants respectfully traverse.

The inability of Church to teach the methods recited in the independent claims is discussed above. Sun does not remedy these deficiencies. For example, Sun does not disclose a method of inhibiting percutaneous absorption of a drug that has been topically administered as recited in claim 1, does not disclose a method of removing a drug from a reservoir thereof in the

skin as recited in claim 5, and does not disclose a method of reducing the effect of overdose of transdermally administered drug as recited in claim 16. Instead, Sun teaches methods of administering active agents or of extracting interstitial fluids from the skin for diagnostic purposes.

Sun et al. is cited for teaching a membrane coated with a layer of adhesive. However, Sun does not teach or suggest a method whereby drug is removed from the skin through the adhesive layer of its device, as recited in the instant claims.

Sun's device is provided with ***blades*** that form ***channels*** in the skin to permit ***delivery of drugs*** or ***withdrawal of interstitial fluids***. Although Sun's device may include adhesive on the blades and other surfaces of the device, compounds do not flow through the adhesive into the device. Instead, the blades of Sun's device disrupt the stratum corneum of the skin of the subject to create open pathways for drugs to flow out of the device into the skin, or for interstitial fluid to flow out of the skin into the reservoir. Thus, Sun does not teach or suggest a device having an adhesive layer as claimed, or a method as claimed where drug is extracted from the skin through an adhesive layer.

For at least the foregoing reasons, the combination of Church and Sun would not lead one skilled in the art to the claimed invention. Applicants therefore respectfully request withdrawal of the §103 rejection based on Church and Sun.

Claim 10 is rejected as being obvious over Church in view of U.S. 2003/0082219 by Warren et al. Applicants respectfully traverse.

The inability of Church to teach the methods recited in the independent claims is discussed above. Warren does not remedy these deficiencies. Indeed, Warren is directed to articles for ***delivering*** skin care compositions to external or internal areas of the skin, not for extracting drugs as claimed.

Claim 10 recites embodiments where the recited device is applied to the site of transdermal administration within 24 hours of transdermal administration of the drug. The Office Action cites claim 20 of Warren against this claim. However Applicants respectfully believe that this reflects an inaccurate reading of Warren or claim 10.

Claim 20 of Warren defines how much of the skin care composition is transferred from the article onto the skin surface during a 24 hour application period, while the article is worn by the subject. Thus, Warren's claim 20 refers to a ***duration*** of contact. By contrast, Applicants' claim 10 describes the timing of administration of the device relative to the time of administration of the drug. Thus, claim 10 recites a time of administration, not a duration of contact. Warren's claim 20 is therefore not relevant to the patentability of claim 10.

Applicants therefore respectfully request withdrawal of the rejection of claim 10.

Claim 15 is rejected as being obvious over Church in view of U.S. Patent No. 6,238,693 to Luther et al. Applicants respectfully traverse.

The inability of Church to teach the methods recited in the independent claims is discussed above. Luther does not remedy these deficiencies. Similar to Warren, Luther is directed to articles for ***delivering*** drug transdermallly, not for extracting drugs as claimed.

Claim 15 recites embodiments where the recited membrane remains adhered to the site of transdermal administration for a period of at least 12 hours. The Office Action cites column 3, lines 9-11, of Luther as teaching a membrane adhering to the skin for at least 12 hours. However, as Luther does not remedy the inability of Church to teach or suggest the claimed methods as a whole, the combination of Luther and Church does not suggested the method of claim 15. Applicants therefore respectfully request withdrawal of the §103 rejection of claim 15.

CONCLUSIONS

Applicants believe that the application is in condition for allowance and favorable reconsideration is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance prosecution.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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